

## **REMARKS**

Reconsideration of the application is respectfully requested.

Concerning the Section 112 rejection of claim 4 with respect to an antibody fragment which binds human pancreatic lipase and comprises a CDR3 from sequences recited in claim 4, it is not understood why it is objectionable to recite CDR3 regions without the corresponding CDR1 and CDR2 regions. From the bottom of page 8 of the specification through the middle of page 10, Applicants discuss preferred V<sub>H</sub>H characterized by selected CDR3s. Thus, Applicants are merely, both by explicit statements in the specification and by reciting therein a dependent claim, indicating that particular CDR3s are preferred. It is not apparent why one of ordinary skill would, in view of the instant specification, not believe that Applicants had in their possession the subject matter of claim 4 which is described as preferred embodiments.

With respect to the second 112 rejection, the Office argues that Applicants have not enabled any human dietary lipase other than those against HPL or HGL. As acknowledged by the Office, the specification discloses feeding antibodies HPL and HGL to piglets in combination with a high fat diet. It is submitted that it is not the law that every single human dietary lipase needs to be tested in order to enable the category of human dietary lipases. Indeed, as explained in the application, human pancreatic lipase is the major lipase responsible for lipid conversion in adults, accounting for 48.5% of the hydrolysis of triacylglyceride. Human gastric lipase is responsible for the hydrolysis of 17.5% of meal triacylglycerides. Therefore, the examples account for classes of lipases which constitute a very significant proportion. It is respectfully requested that it is not necessary to test every single lipase, that the present claims are enabled, and that the Section 112 rejection should be withdrawn.

With respect to the Section 103 rejection, the Office points to no teaching in Convents et al., WO 99/46300 that V<sub>H</sub>H antibodies could be used effectively against human dietary lipases. Convents et al. mention on page 20 new options such as V<sub>H</sub>Hs that bind and neutralize redox enzymes, thereby preventing color changes of food products.

On pages 48 and 49, Convents et al. illustrate that anti-RR6 antibodies are able to prevent dye transfer and that the V<sub>H</sub>Hs remain stable in the presence of surfactants, especially mixed surfactants, and can continue to be effective during the use of laundry detergents. It is not apparent why this would lead one of ordinary skill reasonably to believe that they would be successful in human lipases.

Khldadoust et al., U.S. Patent No. 6,558,936 is directed to isolated nucleic acids encoding human lipase proteins and fragments. The nucleic acids and proteins are said to be useful for diagnosis, prevention and therapy of a number of human and other animal disorders. The Office points to no teaching by Khldadoust et al. of V<sub>H</sub>H antibodies and indeed in the Office Action of July 12, 2005, the Office acknowledges that the Khldadoust patent does not disclose a pharmaceutical or food composition comprising an antibody capable of binding specifically to one or more human dietary enzymes wherein the antibody or fragment thereof comprises a V<sub>H</sub>H. As pointed out previously, functionality of V<sub>H</sub>Hs differs from that of traditional antibodies since V<sub>H</sub>Hs lack several of the effector functions. Hence, Applicants submit that it is surprising that the V<sub>H</sub>Hs disclosed in the present invention are still capable of effectively inhibiting lipase activity in vitro and even in vivo in the gastrointestinal tract of a subject, notwithstanding disclosures in the prior art of antagonists such as antibodies to inhibit the activity of the lipase protein.

In view of the foregoing, it is respectfully requested that the application be allowed.

Respectfully submitted,



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